



FROM: Nevada State Board of Pharmacy Inspector

SUBJECT: Self-Assessment Inspection Process

The Board of Pharmacy's established self-assessment inspection process provides management opportunity to review the standards by which the board inspects your operation. The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of pharmaceutical services. An inspection evaluation form must be obtained from the website to self assess compliance with Nevada pharmacy law. An inspector will review the form with you and inspect your facility during ***the month listed on your Inspection Notice.***

The procedure involves the following:

1. At the ***minimum***, print and fill out the self-assessment inspection form found on the website under your designated license type. We cannot evaluate or help you if we don't know what you don't know. Retain the form and have it **readily available** in a packet so **if you are not present** when an inspector arrives, your staff can have it available.
2. An inspector will conduct a review of your operation. Observations, along with your findings, will assure understanding and compliance with Nevada law.
3. Effective 3/28/2014 LCB file R087-13 requires that each dispensing technician/dispensing technician trainee complete 1 hour of in-service training during the 2 year license renewal period. The in-service training must be a Nevada Board of Pharmacy approved jurisprudence program. The certificate of completion must be kept on file for a minimum of 2 years.

Failure to fill out the inspection report suggests either you are not concerned with knowing the law or complying with it.



DRUG STORAGE AREA: (the cover letter must be attached to this completed form.) Circle yes for compliant and no for non-compliant/not applicable. You may make comments as needed.

Clean & maintained in an orderly manner? Yes No

Current license(s) to prescribe/dispense drugs displayed?
NRS 639.1373, 639.2351, 639.23505 NAC 649.742 (i) Yes No

Temperature compatible w/drug storage requirements (59-86° f)? Yes No

Does the facility dispense products required to be stored in a refrigerator prior to dispensing? (if **NO skip to next question**) NRS 639.282, NAC 639.525-527 Yes No

Refrigerator? Yes No

Is it clean? Yes No

Is the temperature proper for the storage of drugs? (36-46 °F) Yes No

Sufficient size? Yes No

Daily temperature log maintained? Yes No

STOCK OF DRUGS:

Are all pharmaceuticals in stock properly labeled? NRS 585.410 - 585.460 Yes No

Name of product? Yes No

Manufacture's name? Yes No

Lot Number? Yes No

Expiration date? Yes No

Are all sterile multi-dose vials dated and discarded after 28 days? NAC 639.67057 Yes No

Are all single use/preservative free (PF) sterile vials, ampules, ..., etc. used for one patient and immediately discarded after being used? NAC 639.67057 Yes No

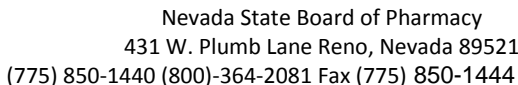
Are outdated, mislabeled, or adulterated drugs removed from stock and secured in an area where they will not be used to fill prescriptions? NRS 639.282, NAC 639.510 Yes No

Is there a procedure for monitoring the stock of drugs for outdated, mislabeled, or adulterated drugs? NRS 639.282, NAC 639.510 Yes No

Are samples and immediate use drugs all in date and labeled properly? NRS 639.282, NAC 639.510 Yes No

CONTAINERS AND LABELING:

Are child resistant, moisture-proof containers used? NAC 639.740, 639.892 Yes No



Yes No

Yes No

Yes No

Yes No

Yes No

Yes No

Yes No

Yes No

Yes No

Yes No

Yes No

Yes No

Yes No

(If the practitioner is not on site during facility hours, the records may be in a separate secure location so they are available for review on inspection)

Electronic

Yes No

Yes No

Yes No

Yes No

Yes No

Yes No

(computer file)

Yes No

Yes No

Yes No

Yes No

Yes No

Yes No

Yes No

Yes No



Does the practitioner maintain the dispensing records properly & retain them for 2 years?

Yes No

Does the facility maintain these records on site? 21 CFR 1304.04 (a)

Yes No

Does the facility dispense controlled substances? (if **NO** skip to security section)

Yes No

Does the facility dispense schedule 2 substances? (if **YES**)

Yes No

Are schedule II prescriptions filed separately from all other prescriptions?

Yes No

Does the facility participate in the Controlled Substance Ordering System (CSOS) for Schedule 2 controlled substances?

Yes No

Are schedule 2 order forms properly completed? 21 CFR 1305.06

Yes No

Are schedule 2 records of receipt (invoices) filed separate from all other invoices?

NAC 453.410

Yes No

Does the facility dispense schedule 3-5 controlled substances?

Yes No

Are schedule III-V records of receipt (invoices) filed separately from all other records?

NAC 453.410

Yes No

How are schedule III-V prescriptions filed NAC 453.480/21 CFR 1304.04 (h)]

(single file) (separate file)
circle method of filing

If in single file: are controlled prescriptions marked in a way to be readily retrievable?

Yes No

Has a biennial inventory of controlled substances been completed? 21 CFR 1304.11, NRS 453.246

Biennial Inventory date or n/a: _____

Yes No

Does facility report all controlled substances dispensed weekly to Nevada controlled substance task force?

Yes No

You are required to submit electronically, weekly, data on all controlled substances dispensed to the Prescription Controlled Substance Abuse Prevention Taskforce Phone: 775-687-5694

Email: ladams@pharmacy.nv.gov How are you submitting the required data?

SECURITY NAC 453.400, NAC 639.285, NAC 639.898, NAC 639.520:

Are controlled substances/dangerous drugs kept in a deadbolt locked storage area?

Yes No

Are licensed practitioner(s) the only person(s) with possession of a key? (review dispensing practitioner regulations for when a dispensing technician may possess the key to the medications)

Yes No

Does the facility have an alarm system? (recommended)

Provider: _____

Yes No

If dispensing controlled substances:

Has there been any theft or loss of controlled substances since the last inspection?

Yes No

(if **YES**): Was the theft or loss of controlled substances properly reported to NSBP, DEA, NDPS? NRS 453.568

Yes No

Are proper drug destruction procedures followed?

21 CFR 1307.21, NAC 639.050

Yes No

Is access to the controlled substance task force data base limited to the practitioner?

Yes No

How is the access protected?



Does each exam room have signage notifying the patient may request that the symptom or purpose for which a drug is prescribed be included on the label of prescriptions you prescribe? NRS 639.2352 Yes No

How are prescription pads secured? _____
Who has access to prescription pads? _____

MANAGEMENT:

Do you have an internet website? Yes No
If yes, what is the web address? _____

Does the Practitioner(s) understand he/she is legally responsible for the dispensing operation? Yes No

Are prescription drugs, previously dispensed to consumers, accepted for return? NRS 639.282 Yes No

List individuals who administer medications in your facility. **(attach a separate list if needed)**
(NAC 639.441 "Administer" defined. (NRS 639.070) "Administer" means the direct application of a drug or medicine, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or the subject of research.)
NRS 454.213 & NRS 454.215 Authority to administer to possess, administer, or dispense dangerous drugs.

Name and License Classification

Is the facility contracted with a vendor to supply computer software or pharmaceutical products? (if YES)

Yes No

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Computer software vendor's Name/Address/Phone #

Pharmaceutical Products vendor's Name/Address/Phone #

Are dispensing technicians and technicians in training records available for inspection? Yes No

- 1) Are you purchasing for sale or dispensing to your patients, from sources other than a Nevada licensed manufacturer of the pharmaceutical product or a Nevada licensed wholesaler, any compounded pharmaceutical product that is available commercially?
a) If you do, provide a complete list of products (Invoices). List the provider(s) of the compounding pharmaceutical product with the provider's complete contact information.

Yes No

- 2) Are you purchasing for administration to your patients, from sources other than a Nevada licensed manufacturer of the pharmaceutical product or a Nevada licensed wholesaler, any compounded pharmaceutical product that is available commercially?
a) If you, provide a complete list of products (Invoices). List the provider(s) of the compounding pharmaceutical product with the provider's complete contact information.

Yes No



- Provide a list of products you are dispensing with the complete contact information on the source you are purchasing the product from.
- How do you verify that the product's provider is licensed to sell to you?
- If you are purchasing compounded products and are not sure if the product is available commercially, contact the provider of the product to verify if the product is available commercially.
- A pharmacy cannot compound a pharmaceutical product for sale to a practitioner for the purpose of resale by the practitioner.
- A pharmacy cannot compound a pharmaceutical product that is available commercially unless there is a significant medical reason for the alteration in the commercial prescription product. Altering includes, but is not limited to, changing one or more inactive ingredients or strength of the active ingredient. The documentation of the reason for altering the commercial product should be noted in the patient's chart and on the written prescription dispensed by the pharmacy.
- AB 537 amended the following Sections 1. NRS 630.306 Sec. 2. NRS 631.3475 Sec. 3. NRS 632.320 Sec. 4. NRS 633.511 Sec. 5. NRS 635.130 Sec. 6. NRS 636.295
- It is a violation of NRS for a practitioner to :
- Knowingly procuring or administering a controlled substance or a dangerous drug as defined in chapter 454 of NRS that is not approved by the United States Food and Drug Administration, unless the unapproved controlled substance or dangerous drug:
 - (a) Was procured through a retail pharmacy licensed pursuant to chapter 639 of NRS;
 - (b) Was procured through a Canadian pharmacy which is licensed pursuant to chapter 639 of NRS and which has been recommended by the State Board of Pharmacy pursuant to subsection 4 of NRS 639.2328; or(c) Is marijuana being used for medical purposes in accordance with chapter 453A of NRS.

Currently there are no Canadian pharmacies licensed by the Nevada State Board of Pharmacy.

Remarks:

[illegible]



If you are required to provide any documentation to the inspector via fax or email attach a copy of the document(s) to this inspection form for future review.

Your drug dispensing practice has been inspected by an agent of the Nevada State Board of Pharmacy. The results of this inspection are noted above. Conditions that are unsatisfactory or need improvement must be corrected within the time frames stated to ensure compliance with the laws/regulations governing the practice of pharmacy.

I understand that I am required to personally order all medications that I will dispense, check in the medications on arrival and also understand that I must secure all medications that I dispense so that no person has access to the medications that I dispense under my dispensing practitioner registration, except as allowed under NAC. All invoices for medications must be invoiced to me personally. (NAC 639.732) I also understand that I can only dispense medications that I prescribe, not medications prescribed by another practitioner.

I also understand that I must keep a log of who is assigned to be my dispensing technician on a particular day. (Ratio of 1:1 practitioner to dispensing technician)



I acknowledge the noted unsatisfactory conditions have been explained to me and I have received a copy of this inspection report.

Inspector: _____ Dated: _____

Practitioner/or authorized agent: _____ Dated: _____

If signed above by an authorized agent, this inspection approval is not valid until the practitioner signs, dates and faxes this page to the inspector.

I understand that I am responsible for compliance with all dispensing practitioner NAC's and NRS's and that each practitioner in the facility that dispenses must have a dispensing practitioner license. (each dispensing practitioner must sign, print name and date)

Practitioner: _____ Dated _____

Practitioner: _____ Dated _____

Practitioner: _____ Dated _____

Practitioner: _____ Dated _____

Practitioner: _____ Dated _____

It is the responsibility of each practitioner to review this inspection form and contact the inspector with any questions the practitioner may have any on deficiencies or notations made by the inspector. It is each practitioner's responsibility to make sure all deficiencies are corrected.

Important: If your dispensing practitioner(s) are not on site all hours that your facility is open, please keep all dispensing records, invoices and documents in a secure location separate from the medications that are being dispensed. The key to this secure area can be kept in a secure area for access to records by the inspector when the practitioner is not on site.